REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 66 is requested to be cancelled.

Claims 3, 9, 64 are currently being amended. Support for the amendments to claims 3 and 9 can be found throughout the specification as-filed, including page 7, first full paragraph. Support for the amendment to claims 64 can be found throughout the specification as-filed, including page 6, sixth full paragraph. No new matter is being added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. These amendments will require no additional searching by the examiner and place the claims in better condition for appeal. Thus, entry thereof is respectfully requested.

After amending the claims as set forth above, claims 1-18, 20, 23, and 62-65 are now pending, and claims 1, 2, 11, 14-18, 20, and 23 are withdrawn. Thus, claims 3-10, 12, 13, and 62-65 will be under examination.

I. Priority/Claim Rejections Under 35 U.S.C. § 112, First Paragraph (New Matter)

The Examiner argues that the present invention is not entitled to receive the benefit of an earlier filing date under 35 U.S.C. § 120, because "the phrase 'having at least 97% sequence identity to the amino acid sequence of SEQ ID NO: 4' which is not supported by the written description in the prior application or this application..." (Office action at 2). Accordingly, the Examiner requires Applicants to file a new oath or declaration with surcharge and designate the current application as a continuation-in-part. Similarly, 3, 6, 7-10, and 62-65 stand rejected under 35 U.S.C. § 112, first paragraph, the examiner argues that the phrase "at least 97% sequence identity with SEQ ID NO: 4" is new matter. Applicants

respectfully disagree with the Examiner denying the present application the benefit of priority and traverse the new matter ground of rejection.

It should be noted at the outset that the present case is a continuation of application number 08/390,740 filed on 17 February 1995. In other words, both the present application and the '740 application share a common disclosure. Thus, if the language deemed objectionable has support in the present application, it must necessarily have support in the parent application. The Examiner does not appear to dispute this point. Office action at 2 ("which is not supported by the written description in the prior application or this application" (emphasis added)). Thus, the issue dispositive to both the denial of the benefit of priority and the new matter rejection is whether or not the present specification contains a written description of the subject matter deemed objectionable by the examiner.

Applicants note that the written description requirement is not an *in haec verba* requirement but instead is meant to require patent applicants to demonstrate possession of the claimed invention. *See* MPEP 2163(I)(B). The claims can be supported by express, implicit, or inherent disclosure. *Id.* Thus, the "[m]ere rephrasing of a passage does not constitute new matter." MPEP § 2163.07(I). Applicants are entitled to use any language, regardless of whether or not the language appears verbatim in the specification as-filed, to claim their invention so long as the as-filed specification demonstrates possession of the claimed invention. MPEP § 2163.02.

While not acquiescing that such a sequence does not support the recitation "97%", the claims have been amended to recite "96%". As noted in the Amendment filed December 20, 2004, the specification states that "'insertions' or 'deletions' are typically in the range of about 1 to 5 amino acids." Specification at page 6, last full paragraph. SEQ ID NO: 4 is 134 bp in length. Thus, a substitution of 5 amino acids would result in a sequence that is about 96.2% identical to SEQ ID NO: 4. Thus, the specification contains support for the recitation "having at least 96% sequence identity to the amino acid sequence of SEQ ID NO: 4."

The Examiner argues that the phrase lacks support, because the "[a]lignment of sequences with insertions and deletions is highly dependent upon the scoring parameters used

in the alignment algorithm." Office action at 5. However, one of skill in the art would readily understand that Applicants had possession of a sequence "having at least 96% sequence identity" to SEQ ID NO: 4 based on the as-filed specification and the specific passage cited above. The fact that percent identity can be altered by manipulating algorithms does not prevent Applicants from simply rephrasing a statement in the specification, "'insertions' or 'deletions' are typically in the range of about 1 to 5 amino acids," to describe the claimed invention.

The Examiner further argues that "the portion of the specification relied upon does not limit the number of insertions or deletions to one to five amino acids that can be present within variants of the disclosed species." Office action at 6. However, Applicants do not need to expressly disclaim subject matter or provide definite and immovable guidelines to support claimed features. The specification clearly states that up to five amino acid insertions or deletions are typical, thus showing that Applicants possessed such variants. Accordingly, the language is sufficient to satisfy the written description requirement.

For at least these reasons, Applicants respectfully request the benefit of the parent application's priority date and respectfully request reconsideration and withdrawal of the new matter rejection.

II. Claim Rejection 35 U.S.C. §§ 101, 112, First Paragraph – Utility

Claims 3-10, 12, 13, and 62-66 stand rejected under 35 U.S.C. § 101, because the claimed invention is allegedly "not supported by either a specific and substantial utility or a well established utility." Similarly, the examiner rejects claims 3-10, 12, 13, and 62-66 under 35 U.S.C. § 112, first paragraph, because in the alleged absence of utility, one of skill in the art would not know how to use the invention. Applicants respectfully traverse these grounds of rejection.

MPEP § 2107(II) states that "an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention" (emphasis added). Additionally, an applicant needs to "establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention." On the basis of the above recited

MPEP sections, the original specification and the post-filing references of record, the subject matter of the present application possesses specific and substantial utility as required under 35 U.S.C. § 101.

A. The Claimed Polypeptides Are Chemokines

As noted in the previous Amendment, the claimed polypeptides and polynucleotides encoding them are pancreatic expressed chemokines. *See e.g.*, specification at 5, first full paragraph. This is a "specific and substantial utility" as required by the statute, and one of skill in the art would know what is meant by a chemokine and how to use such chemokines. Indeed, the post-filing date art cited by the examiner, Nagira *et al.*, *J. Biol. Chem.* 272:19518-24 (1997) ("Nagira"), verifies that the chemokine that they identified "is specifically chemotactic for lymphocytes." Nagira at 19519, first full paragraph.

The Examiner argues that the mere teaching that the claimed polypeptides and polynucleotides encoding them are chemokines fails to satisfy the utility requirement, because further experimentation would be required to determine the target molecule or molecules. Office action at 8. However, Applicants need not provide the mechanism by which the chemokines operate. It is sufficient that they be described as chemokines, because one of skill in the art would be able to use such chemokines, such as in assays.

B. The Claimed Polypeptides Are Chemokines That Can Lead To Activation Of T Lymphocytes

In addition to stating that the claimed polypeptides and polynucleotides encoding them are chemokines, the specification states that the chemokines "can lead to activation of ...T lymphocytes... and/or other cells...." This assertion is further supported by Nagira as noted above. A chemokine that leads to the activation of T lymphocytes would have both specific and substantial utility to one of skill in the art. Applicants note that "an applicant need only provide <u>one</u> credible assertion of specific and substantial utility for each claimed invention." MPEP § 2107(II) (emphasis added).

The Examiner dismisses this language as "suggestive." However, Applicants need not provide an absolute statement of utility. It is sufficient to provide a statement of how the

chemokines "can" be used. In addition, the passage clearly states that expression of chemokines will result in some kind of immune system cell activation, even assuming arguendo that the passage does not unequivocally provide the exact target(s). Such a statement is sufficient to establish utility of the claimed invention, because one of skill in the art would readily understand how to use compounds, which activate immune cells.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 3-10, 12, 13, and 62-66 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

III. Claim Rejection 35 U.S.C. § 112, first paragraph – Written Description

Claims 3, 6-8, 9, 13, 62, 64, 65, and 66 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Essentially, the claims were rejected because variants, biologically active fragments, and immunogenic fragments of SEQ ID NO. 4 are allegedly not described in the instant specification. Applicants respectfully traverse this ground of rejection.

As noted in the Amendment filed December 20, 2004, a skilled artisan would understand the as-filed specification to demonstrate possession of a polypeptide variant sharing at least 96% sequence identity to SEQ ID NO: 4 and possessing chemokine activity. Because of the redundancy in the genetic code and the teachings in the application, a skilled artisan would know what nucleotides to change to encode a polypeptide that corresponds to the amino acid sequence of SEQ ID NO: 4. Additionally, a skilled artisan would know what amino acid substitutions could be made to SEQ ID NO: 4 so as to preserve the chemokine functionality of the protein. And since part b) of the claim recites at least 96% sequence identity to SEQ ID NO: 4, only a small number of substitutions could be made thereby limiting the number of species encompassed. One of skill in the art can readily determine and screen compounds for chemokine activity as evinced by Example XII, for example. Specification at 21.

The specification also demonstrates possession of biologically active and immunogenic fragments consisting essentially of SEQ ID NO: 4, such as on page 7, first full

paragraph. The claimed fragments also have chemokine activity and the functionality of the fragment can then be determined based on known methods. Indeed, chemokines are known compounds in the art and one of skill in the art would know how to assess whether a given protein has chemokine activity. In addition, the specification provides an example of how to screen for biological activity. Specification at 21, Example XII.

The Examiner argues that an insufficient number of species are disclosed to provide written description support for the genus. However, the specification provides the specific examples of SEQ ID NOS: 3 and 4. In addition, the claimed genus is defined in structural terms (96% sequence identity) and/or functional terms (chemokine activity). The structural recitation limits the variation from SEQ ID NO: 4 to a very small number of amino acid modifications. The ability to screen for chemokine activity is well-known in the art as illustrated by the teachings of the specification, as noted above. Thus, a large number of specific examples are not needed in light of the claimed features and the knowledge of the skilled artisan as supplemented by the specification.

The Examiner further argues that the specification does not demonstrate possession because the specification allegedly does not describe the precise function of the claimed chemokines. Office action at 21-22. However, the specification describes assays for chemokine activity in general (Example XII). One of skill in the art would be aware of additional assays to screen for chemokine activity in general. Thus, Applicants do not need to describe the precise chemokine function to demonstrate possession of the claimed invention.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Claim Rejections – 35 U.S.C. § 112, Second Paragraph – Definiteness

Claims 64 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. The Examiner argues that claim 64 is indefinite, because it recites "having one or more conservative amino acid substitution(s)" without reciting "a reference sequence with which the substitutions are relative to...." Office action at 17.

While not acquiescing in the propriety of this ground of rejection, Applicants have amended claim 64 to "recite a reference sequence." Thus, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

V. Claim Rejections – 35 U.S.C. § 102

A. WO 92/09629 to Caput *et al.*

Claims 3, 6-9, and 66 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 92/09629 to Caput *et al.* ("Caput"). According to the Examiner, Caput teaches "an isolated nucleic acid encoding a biologically active fragment of a polypeptide that consists of the amino acid sequence of SEQ ID NO: 4 wherein said fragment is [*sic*] has chemokine activity." Office action at 17. Applicants respectfully traverse this ground of rejection.

While not acquiescing to the propriety of the rejection, claims 3 and 9 have been amended to recite that the biologically active fragment is "at least 5 amino acids in length" and claim 66 is cancelled. Support for this amendment can be found throughout the specification as-filed, including page 7, first full paragraph. The fragment of Caput is only four amino acids in length. Thus, Caput's 4 amino acid fragment cannot anticipate the claimed fragment, which is at least 5 amino acids in length. Similarly, claims 6 and 7, which are dependent on claim 3, are also novel over Caput.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection against claims 3 and 6-9. Applicants also note that the rejection of claim 66 is rendered moot by the cancellation of claim 66.

B. Hromas *et al.*, J. IMMUNOL. 159(6):2554-2558 (1997)

Claims 3, 6-9, 10, 62, 63, 64, and 65 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hromas *et al.*, J. IMMUNOL. 159(6):2554-2558 (1997) ("Hromas") as evidenced by GenBank Accession No. U88320 (18 December 1997). Applicants respectfully traverse this ground of rejection.

Hromas cannot anticipate the claimed invention, because it is not prior art to the claimed invention. As noted above in Section I, the present application is a continuation of application no. 08/390,740, filed on 17 February 1995, and is entitled to the benefit of the 17 February 1995 filing date under 35 U.S.C. § 120. Thus, Hromas is not prior art to the claimed invention, because Hromas was not published until after the priority date of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 6/21/05 By _____

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